STUDY OF SUBCUTANEOUS PRESSURE IN CELLULITIS OF THE LEG AND ITS CORRELATION TO THE MANAGEMENT

A dissertation submitted in partial fulfilment of the requirements of

MS (Branch-I) General Surgery examination of the

Tamilnadu Dr. MGR Medical University, Chennai to be held in April 2014.

CERTIFICATE

This is to certify that the dissertation entitled "**Study of subcutaneous pressure in cellulitis of the leg and its correlation to the management**" is a bonafide work by Dr. Abinaya R N, submitted in partial fulfilment of the requirements for the MS General Surgery (Branch I) examination of the Tamil Nadu Dr. MGR Medical University, Chennai, to be held in April 2014.

Signature

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Dr. Sukria Nayak Professor General Surgery	Dr. Benjamin Perakath Professor and Head General Surgery	Dr. Alfred Job Daniel Professor Orthopaedics

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I am grateful to a number of people who have guided and supported me throughout the research process and provided assistance for my venture.

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STUDY OF SUBCUTANEOUS PRESSURE IN CELLULITIS OF THE LEG AND ITS CORRELATION TO THE MANAGEMENT A dissertation submitted in partial fulfilment of the requirements of M.S (Branch-I) General Surgery examination of the TamilNadu Dr. MGR Medical University, Chennai to be held in April 2014. CERTIFICATE This is to certify that the dissertation entitled "Study of subcutaneous pressure in cellulitis of the leg and its correlation to the management" is a bonafide work by Dr. Abinaya R N, submitted in partial fulfilment of the requirements for the M.S.General Surgery (Branch I) examination of the Tamil Nadu Dr. MGR Medical University, Chennai, to be held in April 2014. Signature Guide Dr. Sukria Nayak...

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February 20, 2012

Dr. Abinaya R N
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Sub: **FLUID Research grant project NEW PROPOSAL:**
Study of Subcutaneous pressure in patients with unilateral cellulitis of the leg.
Dr. Abinaya R N, PG Registrar, General Surgery, Dr. Sukriya Nayak, Dr. Mark Ranjan Jesudason, Dr. Rohin Mittal, General Surgery – Unit II

Ref: IRB Min. No. 7711 dated 12.12.2011

Dear Dr. Abinaya,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Study of Subcutaneous pressure in patients with unilateral cellulitis of the leg" on December 12, 2011.

The Committees reviewed the following documents:

1. Format for application to IRB submission
2. Patient Information Sheet and Consent Form (English and Tamil)
3. Cvs of Dr. Abinaya, Rohin Mittal, Mark Ranjan Jesudason
4. A CD containing documents 1 - 3

The following Institutional Review Board (Ethics Committee) members were present at the meeting held on December 12, 2011 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore- 632002.

Name	Qualification	Designation	Other Affiliations
Dr. B.J.Prashantham	MA (Counseling), MA (Theology), Dr Min(Clinical)	Chairperson(IRB)& Director, Christian	Non-CMC

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INSTITUTIONAL REVIEW BOARD (IRB)
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		Counselling Centre	
Mr. Harikrishnan	BL	Lawyer	Non-CMC
Mrs. S. Pattabiraman	BSc, DSSA	Social Worker, Vellore	Non-CMC
Mrs. Ellen Ebenezer Benjamin (on behalf of Dr. Jayarani Premkumar)	M.Sc. (Nursing), Ph.D.	Nursing Superintendent, CMC.	
Dr. Gagandeep Kang	MD, PhD, FRCPath.	Secretary IRB (EC)& Dy. Chairperson (IRB), Professor of Microbiology & Addl. Vice Principal (Research), CMC.	

We approve the project to be conducted as presented.

The Institutional Review Board expects to be informed about the progress of the project, any serious adverse events occurring in the course of the project, any changes in the protocol and the patient information/informed consent and requires a copy of the final report.

A sum of ₹ 80,000/- (Rupees Eighty thousand only) is sanctioned for two years.

Yours sincerely

Dr. Alfred Job Daniel
Principal& Chairperson (Research Committee)
Institutional Review Board

Chairperson (Research Committee) &
Principal
Christian Medical College
Vellore - 632 002, Tamil Nadu, India

ABSTRACT

Title of the abstract: Study of subcutaneous pressure in cellulitis of the leg and its correlation to the management.

Objective: To correlate the subcutaneous pressure with surgical intervention in cellulitis of the leg.

Methods: An observational study with a sample size of 28 patients with cellulitis of the leg affecting one side. The subcutaneous pressure was measured in normal and cellulitic leg in recruited patients. The subcutaneous pressure was correlated to the management. Statistical analysis was done to find out the correlation between the increase in subcutaneous pressure and surgical intervention in cellulitis of the leg.

Results: The increase in subcutaneous pressure in cellulitic leg in group of patients who underwent surgery when compared to the group of patients who were managed conservatively was statistically significant.

CONTENTS

1. INTRODUCTION

1. INTRODUCTION

Cellulitis is an infection of skin and subcutaneous tissue. It results in inflammatory process causing fluid accumulation in the subcutaneous space with erythema of the skin, local warmth and tenderness(1). Most common cause is the bacterial infection but rarely fungal infection can also cause cellulitis. The incidence of cellulitis is more in middle aged and elderly population. In western population males are affected more than females. The lower extremity is the most common site for cellulitis in adults(1).

Lower limb cellulitis often results in prolonged hospitalization and long term morbidity. Almost one quarter of the patients with lower limb cellulitis required hospitalization. The mean duration of inpatient treatment for lower limb cellulitis was 10 days(2). The long term morbidity includes chronic edema, persistent leg ulceration and 29% of the population who had cellulitis of the leg will have recurrence within 3 years(3).

The most common bacterial organism causing cellulitis is the skin commensals like streptococci and staphylococci. The site of breach in skin integrity is the point of entry of the organisms. The infection pathogenesis is worsened due to associated comorbidities like Diabetes mellitus, chronic renal disease, lymphedema and other immune compromised conditions.

Cellulitis is usually managed conservatively with antibiotics and limb elevation. The surgical intervention is required in case of local complications like abscess, necrotizing soft tissue infection and systemic complications like severe sepsis with multiple organ involvement.

There is a lack of good evidence based literature for the management of patients with lower limb cellulitis. It is an important healthcare issue due to the loss of work and financial burden for patients because of the prolonged hospital stay and long term morbidity. There are no standardized guidelines for the management of lower limb cellulitis. In clinical practice it is variable depending on the experience of treating physician/surgeon.

2. AIMS AND OBJECTIVES

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AIMS

- To measure subcutaneous pressure in cellulitis of the leg.
- To correlate subcutaneous pressure with the surgical intervention in cellulitis of the leg.

OBJECTIVES

- To measure subcutaneous pressure in cellulitic leg and compare it to the normal leg.
- To correlate the increase in subcutaneous pressure with surgical intervention in cellulitis of the leg.

3. LITERATURE REVIEW

3. LITERATURE REVIEW

Cellulitis is an infection of skin and subcutaneous tissue, usually from an acute infection caused by skin flora. It usually follows a breach in the skin, although the port of entry may not be obvious always and it depends on the invasive nature of organisms.

EPIDEMIOLOGY

The incidence of cellulitis is 24.6/ 1000 person- years according to a population based survey conducted in USA(1). Cellulitis is more common in males and the incidence increases with age. In another population based survey the incidence of lower limb cellulitis was more than 20%. Amongst these, 20% of the patients had recurrence within2 years(4).

PREDISPOSING FACTORS

- Breach in the skin continuity due to trauma, insect bite or puncture wound
- Skin lesions like web space intertrigo, tineapedis or dermatitis
- Burns
- Venous insufficiency
- Lymphatic edema
- Bilateral pitting pedal edema in congestive heart failure and renal failure
- Diabetes mellitus
- Immunocompromised state
- Previous cellulitis

CAUSATIVE ORGANISMS

Bacterial organisms are the most common organism causing cellulitis. Rarely fungi can cause cellulitis in immune compromised patients and in drug abusers.

Common causes

- Group A β-hemolytic streptococci (Streptococcus pyogenes)
- Staphylococcus aureus

- Haemophilus influenzae
- Group B, C, D, or G β-hemolytic streptococci

Rare causes

- Gram-negative bacilli - Escherichia coli and Pseudomonas
- Streptococcus agalactiae
- Pasteurella multocida infection most commonly occurs following dog bite
- Capnocytophaga canimorsus (dog bites)
- Eikenella corrodens&Bacteroides species (animal bites and human bites)
- Peptostreptococcus (human bites)
- Aeromonashydrophila and Vibrio vulnificus infection (salt water infection)
- Mixed aerobic-anaerobic flora
- Enterobacteriaceae
- Enterococcus
- Fungi in immune compromised hosts and intravenous drug users
- Atypical mycobacterium
- Clostridium perfringens

PATHOGENESIS

There are various theories in the pathogenesis of cellulitis. The most common cause is the break in skin integrity especially the toe web space, which causes the normal skin flora to colonize and lead to subcutaneous infection. In case of patients with underlying risk factors, especially pre-existing edema due to venous or lymphatic obstruction even low concentration of pathogenic bacteria or normal skin flora can cause cellulitis(5). The streptococci and staphylococci produce exotoxins which causes inflammatory mediator release, resulting in the edema and skin changes(6).

In case of immune compromised individuals or with fungal skin infection, the fungal antigens combine with the bacterial toxins and lead to the inflammatory response(6).There are animal studies which have shown that the exotoxins produced by streptococci resulted in cellulitis because of the hypersensitivity reactions and not due to direct toxic effects(7).

If the infection is left untreated the bacteria invades the skin and enter into the subcutaneous tissue and dermal lymphatics. Once it reaches the lymphatic system, it can enter into circulation and cause systemic sepsis. The flesh eating organisms like Streptococci liquefy the fascia and enter into deeper plane,

involving the muscles and tendons. This eventually leads to necrotizing soft tissue infection.

The edema in subcutaneous plane in cellulitis increases if the infection is left untreated or if it is not responding to the antibiotics and anti -inflammatory drugs. The edema fluid acts as a medium for the infection to harbor and invade the deeper tissues(5). If the infection is persisting in the subcutaneous plane, the edema worsens causing the skin to stretch and leading to ischemia of the epidermal layer. This eventually leads to skin necrosis, ulceration and can cause necrotizing soft tissue infection. The venous insufficiency and lymphedema are considered as the most common risk factors for recurrent cellulitis(7).

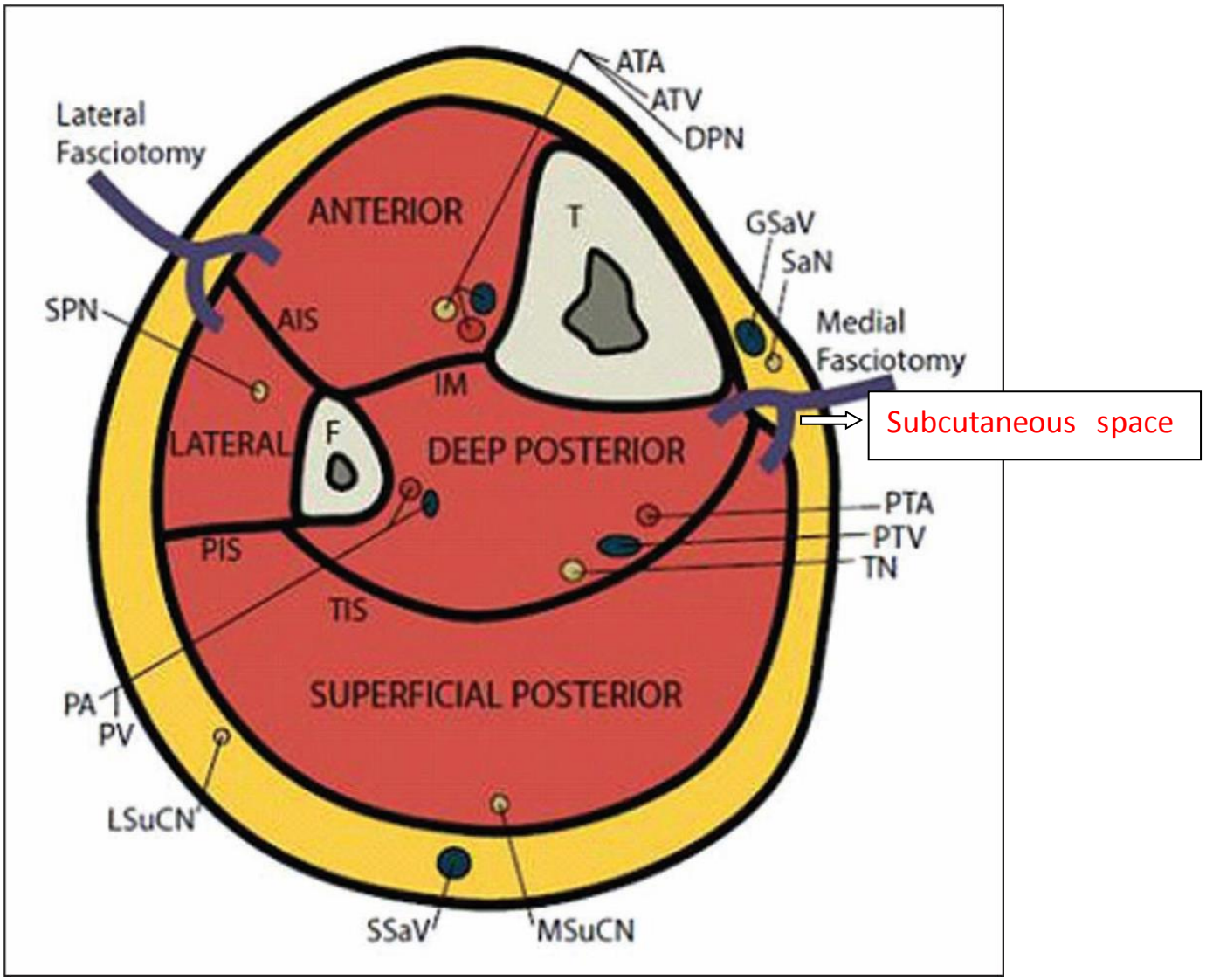

Fig 1: Axial section of the leg showing the subcutaneous space and deep muscular compartment. Subcutaneous space is a closed space and acts like a single compartment.

The subcutaneous edema, as a result of infection and inflammation can lead to increase in subcutaneous pressure as it is a closed space (Fig 1). In this study we measured and compared the subcutaneous pressure in the normal leg and in cellulitic leg. Till date there is no study in literature about subcutaneous pressure changes in cellulitis affecting lower limb.

The normal subcutaneous pressure of the leg varies from -4 to +4mmHg(8). In chronic venous insufficiency the subcutaneous pressure is elevated as a result of edema. Releasing the subcutaneous fluid in chronic venous insufficiency leg decreases the subcutaneous pressure(9). In this study, the proposed theory is increase in subcutaneous pressure in cellulitis of the leg is similar to raised subcutaneous pressure in chronic venous insufficiency of lower limb due to edema. In cellulitis of the leg, there is subcutaneous edema due to infection and inflammation which causes increase in subcutaneous pressure. The raised subcutaneous pressure due to edema results in local complications like skin necrosis and abscess (edema fluid acts as a medium to harbor infections).

The subcutaneous edema and skin manifestations in cellulitis will improve, if the infection responds to the treatment with antibiotics, anti- inflammatory and limb elevation. However, in some cases it can progress to local complications or life threatening systemic infection. In these cases there is

need for surgical intervention like incision and drainage and debridement. In this study, we assessed the correlation between the raise in subcutaneous pressure in cellulitis of the leg with the early surgical intervention.

CLINICAL FEATURES

The most common site of cellulitis in adults is lower limb. The common clinical presentations are pain, swelling of the leg with fever(10). Commonly it is associated with predisposing factors like trauma or insect bite, which can cause break in skin continuity and comorbidities like Diabetes mellitus and immune compromised state. The common signs of presentation are swelling of the leg with warmth and tenderness. Erythema can be appreciated well in fair skin individuals. If there is systemic infection, patients will have high grade temperature, tachycardia and tachypnea. Systemic symptoms like fever and raised white cell counts were present in 42% of the individuals at the time of admission(11).

COMPLICATIONS

Local skin necrosis, tissue loss and abscess formation do occur in severe cellulitis. It can spread to deeper tissues and can result in necrotizing soft tissue infection(11). Factors like male sex, morbid obesity, renal failure, multiple comorbidities, cardiac failure causes progression of infection and affect adversely in resolution of the cellulitis(12). In case of virulent infecting organism, it can lead to systemic sepsis and present with shock and multiple organ dysfunction. The complication rate was higher in patients with the history of previous cellulitis, increased white cell counts, and elevated CRP(13). The lymphatic involvement leads to destruction of lymphatics which causes lymphedema of the affected areas and prone for recurrent cellulitis.

DIFFERENTIAL DIAGNOSIS

- DVT
- Necrotizing fasciitis
- Drug reactions
- Gas gangrene
- Contact dermatitis

DIAGNOSIS

Cellulitis is usually diagnosed based on clinical manifestations. The elevated white cell counts, raised CRP and ESR were considered as the predictors for complications and prolonged length of hospital stay (13). There were studies in the past to find out the pathogen from the needle aspirate culture and fluid/ pus culture from blebs in cellulitis of the leg. The yield of pathogen was less in these cultures. In case of systemic sepsis with recurrent cellulitis or not responding to the traditional antibiotics, blood culture can be done to identify the pathogen. The blood cultures were positive in less than 5% of all cases(14).

MANAGEMENT

Cellulitis is usually managed medically unless there are local and systemic complications. Conventionally the need for surgical intervention in cellulitis of the leg is abscess and progression to necrotizing soft tissue infection. Medical management includes antibiotic, anti-inflammatory medication and anti-edema measures like limb elevation and magnesium sulphate paste local application. The common organisms causing cellulitis of the leg are staphylococci and beta hemolytic streptococci. Patient with lower limb cellulitis were started with empirical antibiotic covering these two organisms. The duration of antibiotic treatment depends on the clinical response. In case of mild infection, usually it responds to oral antibiotics. In case of moderate to severe infection parenteral antibiotics are needed.

Cellulitis with no abscess or purulent discharge are managed with empirical antibiotic therapy against beta hemolytic streptococci and methicillin susceptible staphylococci(15). The most common oral antibiotics used were Dicloxacillin, Cephalexin and Clindamycin for beta hemolytic streptococci and MSSA infection. The commonly used parenteral antibiotics were Oxacillin, Naficillin, Cefazolin and Clindamycin for beta hemolytic streptococci and MSSA infection(16).

The duration of antibiotic treatment depends on the clinical response and it is usually 5to 10 days. The longer duration of antibiotic therapy may be needed in patient with severe infection or systemic toxicity(16).

The most common cause for cellulitis with exudate and purulent discharge is MRSA. In case of purulent cellulitis, the antibiotics should be targeted for methicillin resistant staphylococci infection. The common antibiotics used for MRSA are Linezolid, Clindamycin or Vancomycin(15).

There are no criteria or evidence in literature for surgical intervention in cellulitis. The surgical intervention like drainage/ debridement/ fasciotomy is usually performed when there are complications like ascending infection, worsening of symptoms, evidence of necrotizing soft tissue infection and severe systemic toxicity.

The early surgical intervention like incision and drainage/debridement might show faster improvement in ascending infection not responding to antibiotics and it can also decrease the hospital stay. The problem with surgical intervention is the raw area which needs dressing and there is risk of secondary infections. There are no studies in literature to prove surgical

management is superior to antibiotic therapy. There are no definitive criteria or predictors for early surgical intervention. It is a subjective assessment made by the surgeon to operate in cellulitis of the leg.

STUDY BACKGROUND

Our institute data for the management of cellulitis of the leg in the past one year was retrospectively analyzed and we found that the management of cellulitis can be grouped into three. One group was managed with only antibiotics, the second group was managed with surgical intervention and antibiotics and third group was managed with antibiotics initially and then surgical intervention. The latter was because of worsening of symptoms with local ascending infection and systemic sepsis indicating failure of conservative management.

Hence we decided to study the pressure in subcutaneous space in the cellulitic limb and look at its correlation with surgical intervention. The subcutaneous pressure in cellulitic leg was compared with the normal leg of the same individual. The subcutaneous space is considered as a closed single compartment as anatomically there are no septa or fascia dividing it (Fig 1). But in cellulitis mostly the swelling, warmth, erythema and tenderness will be confined to one area of the leg rather than a circumferential involvement. Usually cellulitis is confined to one area and then spread circumferentially in the subcutaneous space.

So we measured the subcutaneous pressure at different points in the cellulitic leg. We also analyzed the statistical significance of difference in subcutaneous pressure in group of patients managed with antibiotic and in surgically intervened group.

4. MATERIALS AND METHODS

4. MATERIALS AND METHODS

This chapter briefly explains the materials used for this study as well as the methodology used.

MATERIALS

The following materials are used in this study:

- Inch tape – to measure the circumference of normal leg and cellulitic leg.
- Local anaesthetic gel: Prilox cream (lignocaine 25mg + prilocaine 25 mg) per gram
- Skin marker
- 7.5% Povidone Iodine solution
- Stryker intracompartmental pressure monitor- 18G side port needle, saline prefilled syringe and pressure diaphragm (Fig 2).

Fig 2: Stryker intracompartmental pressure monitor with 18G side port needle, pressure diaphragm and saline prefilled syringe.

Stryker intracompartmental pressure monitor (Fig 2) is used in measuring the deep compartment pressure in compartment syndrome. The subcutaneous space is a closed space like deep compartment in leg so we used Stryker intracompartmental pressure to measure the subcutaneous pressure.

Boody et al studied the accuracy of arterial manometer, Whitesides apparatus and Stryker pressure monitor in measuring deep compartment pressure in compartment syndrome. It was reported from the study that side port needle and slit catheter were more accurate than straight needle which has a tendency to overestimate the pressure. Arterial manometer and Stryker device are accurate in measuring the compartment pressure(17). So we used Stryker intracompartmental pressure monitor with 18G side port needle to measure the subcutaneous pressure.

METHODOLOGY

Patients with cellulitis of lower limb, affecting one side, below the knee who attended the surgery outpatient clinic or the emergency department of CMC hospital and admitted in the surgery wards were included in this study.

INCLUSION CRITERIA

- Unilateral, cellulitis of the leg only.
- Adults, >18 years of age.

EXCLUSION CRITERIA

- Bilateral pedal edema/ bilateral cellulitis
- Necrotizing fasciitis
- Filarial leg
- Deep vein thrombosis
- Fracture tibia/fibula
- Cellulitis patient already treated with a course of antibiotics
- Diabetic foot with ulcers/ skin necrosis

An informed consent was obtained by the investigator within 24 hours of admission. The circumference of the cellulitic leg at the point of maximum swelling was measured. Black skin marker was used to mark four points anteromedial, anterolateral, posteromedial and posterolateral aspect at the same level. The distance of the point from the tibial tuberosity was measured. The circumference of the normal leg was measured at the same distance from tibial tuberosity and the anteromedial aspect of the normal leg was marked with the marker at the same level. Local anaesthetic gel was applied and 45 minutes later pressure was measured using the Stryker monitor.

Both the legs were cleaned with Povidone iodine solution for sterile precautions to pevent secondary infections. The subcutaneous pressure was measured in the normal leg with Stryker intracompartmental pressure monitor at an angle of 45 degree between the skin and the needle (Fig 3). The needle was 5cm in length. Only the 0.5cm of tip of the needle with the side port was inserted into the subcutaneous space. This will avoid needle from piercing the deep fascia and entering into the intramuscular compartment. The needle was held in the place for 10 seconds and 0.5ml of saline was injected. The stable pressure value was noted.

The subcutaneous pressure was noted in the cellulitic leg at four points at the same level. Patient details and the pressure values were noted in the proforma. The pressure value was not revealed to the treating surgeon. The decision of conservative management with antibiotics or surgical intervention was made by the treating surgeon from the clinical assessment.

Fig 3: Method of measuring subcutaneous pressure in the leg using Stryker pressure monitor. Tip of 18G needle with side port is injected into the subcutaneous space at an angle of 45 degree between the skin and needle.

The patients were followed up at the time of discharge and at 14th day in the outpatient clinic or contacted by phone. The treatment given was documented. The clinical improvement with respect to symptoms and the wound following surgical intervention were assessed during the follow up.

5. ANALYSIS AND RESULTS

5. ANALYSIS AND RESULTS

STATISTICAL ANALYSIS

The statistical significance of the data were analyzed by paired t – test, Mann – Whitney U test, Levene's test of equality of variance and Independent sample t- test. Paired t - test was used to analyze the significance of difference in the subcutaneous pressure at 2 different points in the cellulitic leg. Mann-Whitney U test, a nonparametric version of sample t- test was used to analyze the significance of difference in pressure with respect to the distance from tibial tuberosity. Levene's test of equality of variance was used to rule out the variability between the patients treated conservatively and with surgery. Independent sample t- test was used to analyze the statistical significance of change in subcutaneous pressure between the antibiotic group and surgery group.

RESULTS

The sample size calculated was 36 at the beginning of the study. During the 2 year period 28 patients were recruited for this study. The mean age of the patients included in the study was 59 years.

Age	20 to 30 years	30 to 40 years	40 to 50 years	50 to 60 years	60 to 70 years	70 to 90 years
Number of patients	1	0	3	9	9	6

Table 1: Age distribution of patients in the study group

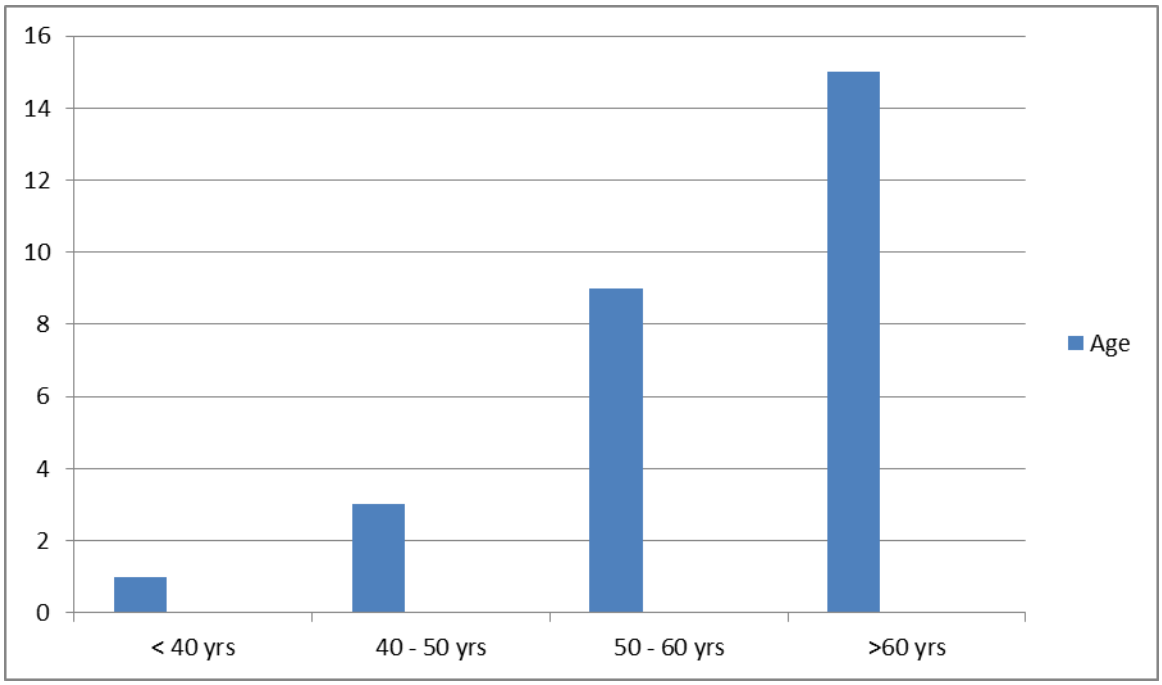

Fig 4: Bar chart showing the age distribution of patients included in this study.

Majority of the patients were elderly more than 60 years of age similar to the literature as shown in Fig 4.

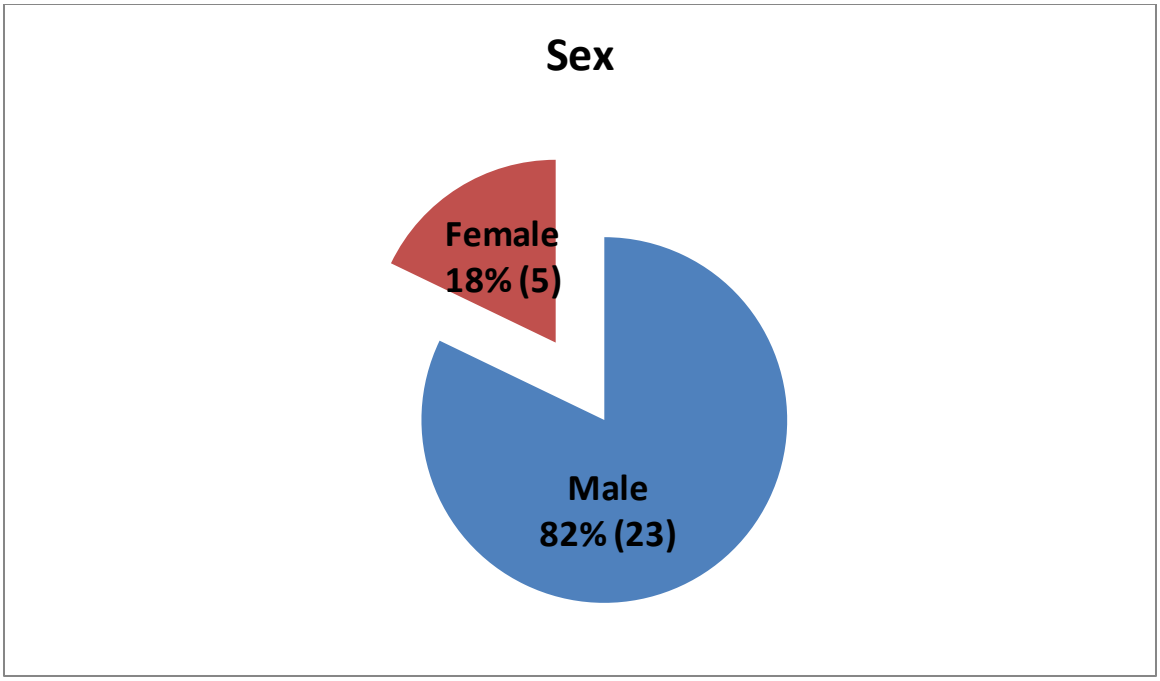

Fig 5: Pie chart showing the sex distribution of patients included in this study.

From Fig 5 one can see that, 82% of the study group was males showing male predominance, similar to the literature.

CLINICAL PRESENTATIONS

The common clinical presentations were pain, swelling and fever. Pain and swelling was present in 100% of the study group and fever was present in 96% of the study group as shown in Fig 6. Most of the patients had medical comorbidities like Diabetes Mellitus, Hypertension and Renal disease.

Symptoms	Pain	Swelling	Fever
No of patients	28	28	27

Table 2: Distribution of symptoms in the study group

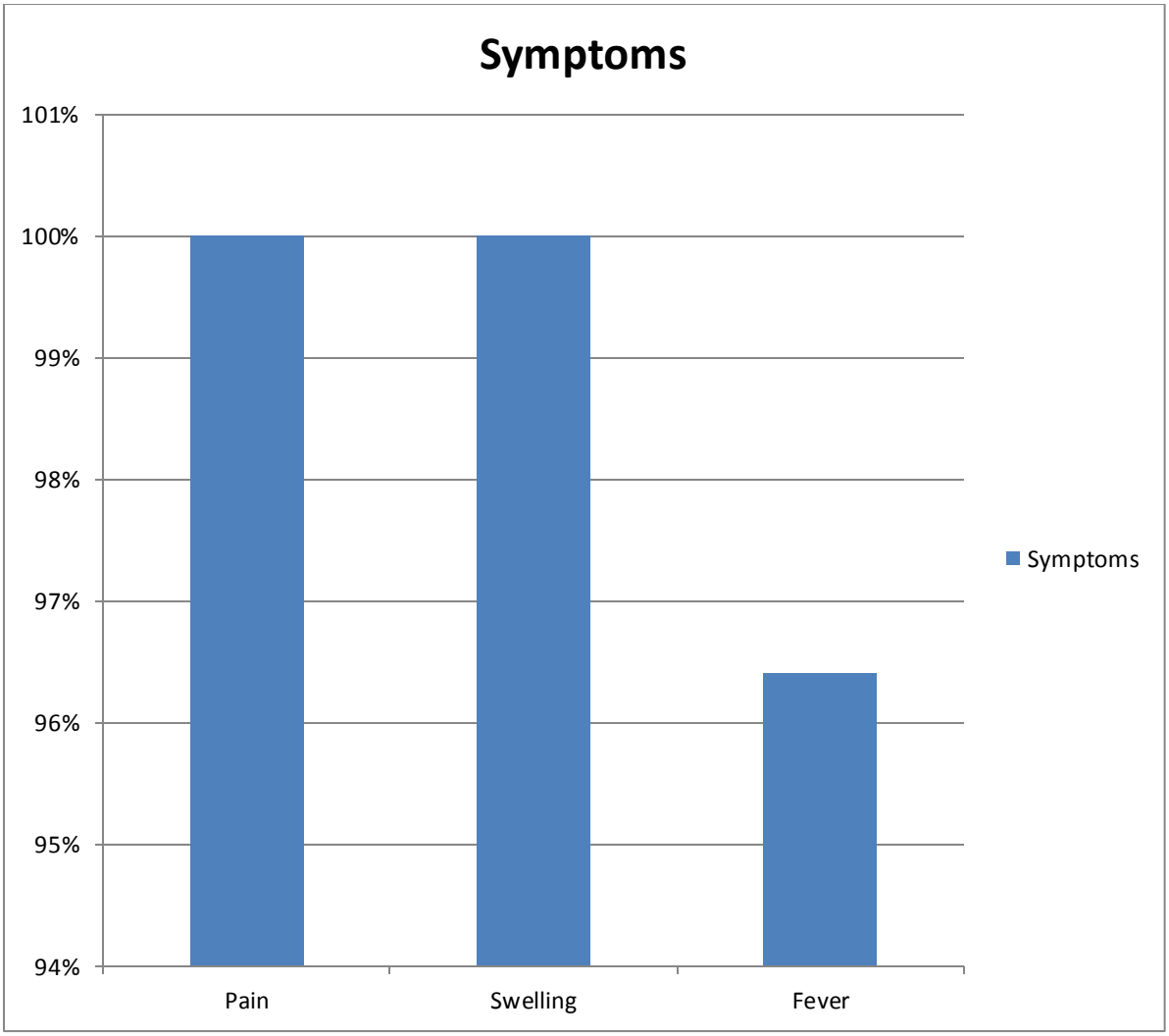

Fig 6: Clinical presentations in the study group.

Comorbid Conditions	Diabetes mellitus	Hypertension	Chronic renal disease
No of patients	18	6	4

Table 3: Distribution of comorbid conditions in the study group

As mentioned in the literature, we found that most of the patients with cellulitis of the leg had medical comorbidities. Fig 7 shows that majority of the patients in the study group had Diabetes mellitus. Diabetes mellitus was present in 64.3% (18) of the study population (Table 3).

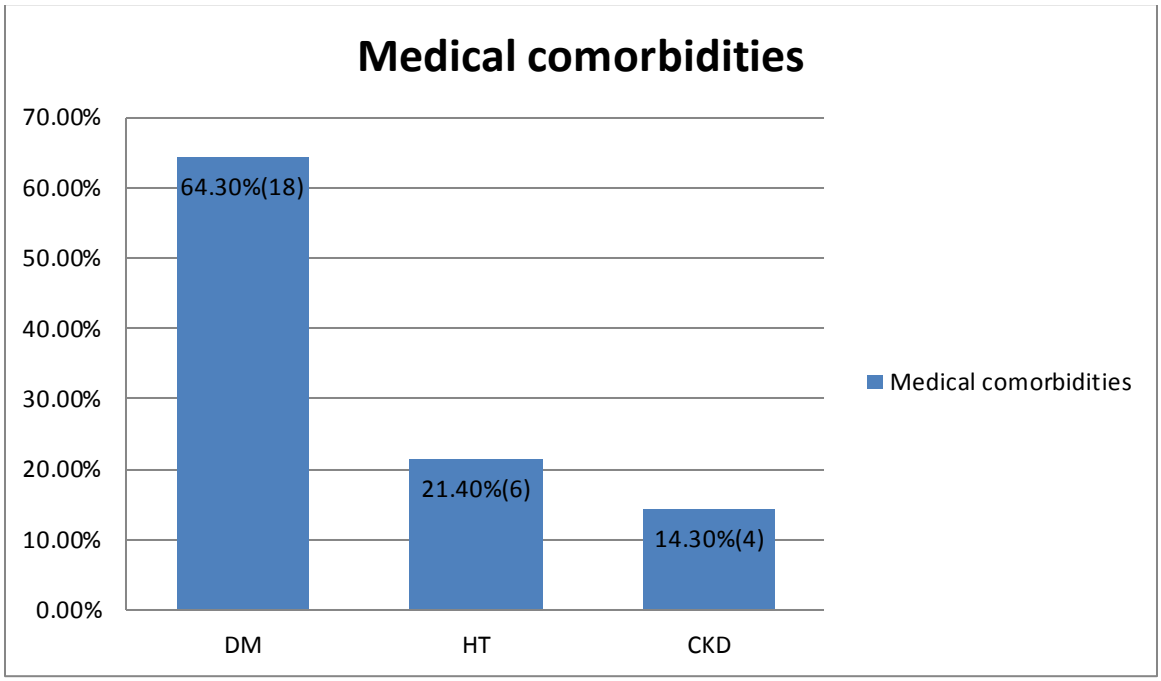

Fig 7: Medical comorbidities – Diabetes mellitus, Hypertension and Renal disease in the study group.

Signs	Frequency	Percentage (%)
Swelling	28	100
Erythema	22	78.6
Warmth	28	100
Tenderness	28	100

Table 4: Signs documented at the time of admission.

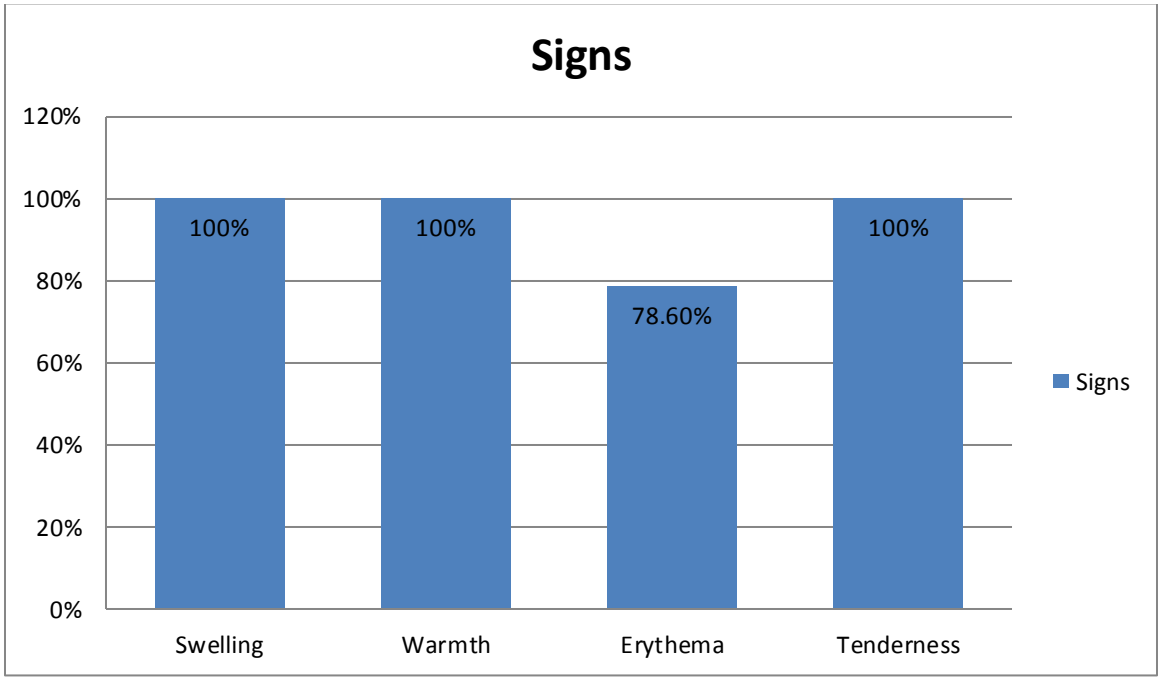

Fig 8: Bar chart showing the distribution of signs in the study group.

The symptoms and signs in the study group were similar to the literature. The signs documented were swelling, erythema, warmth and tenderness. Table 4 shows that, erythema was present only in 78.6% of the study group but swelling, warmth and tenderness were present in the entire study group (Fig 8). Symptoms and signs were used as the clinical indicators to assess the improvement during the treatment.

CIRCUMFERENCE

Measures	Circumference of the normal leg(cm)	Circumference of the Cellulitis leg(cm)	Distance from the tibial tuberosity(cm)
Mean	28.07	31.89	16.43
Minimum	11	13	4.00
Maximum	40	44	30.00
SD	6.27	7.11	5.43
25^{th} percentile	23.25	27.00	13.00
50^{th} percentile	29.00	32.00	15.00
75^{th} percentile	32.75	38.00	19.50

Table 5: Mean of circumference of the normal leg, cellulitic leg and its distance from the nearby bony landmark (tibial tuberosity)

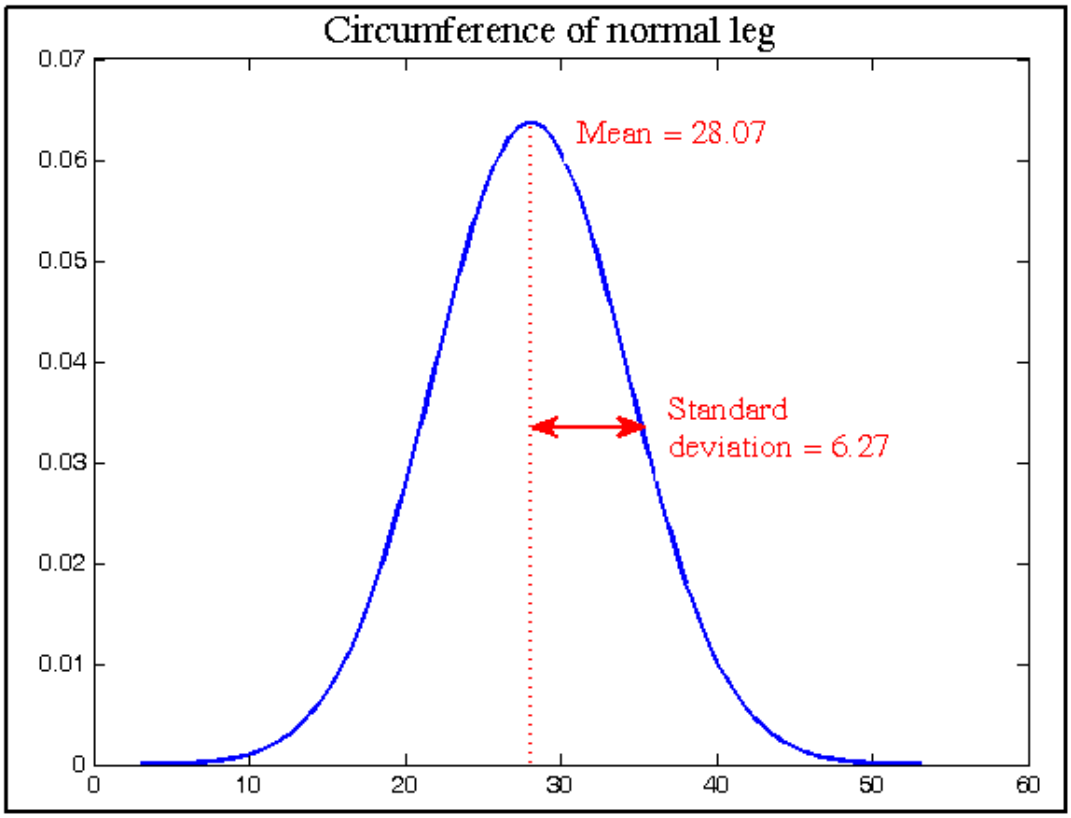

Fig 9: Bell curve with the mean of 28.07cm and standard deviation of 6.07 cm for normal leg circumference

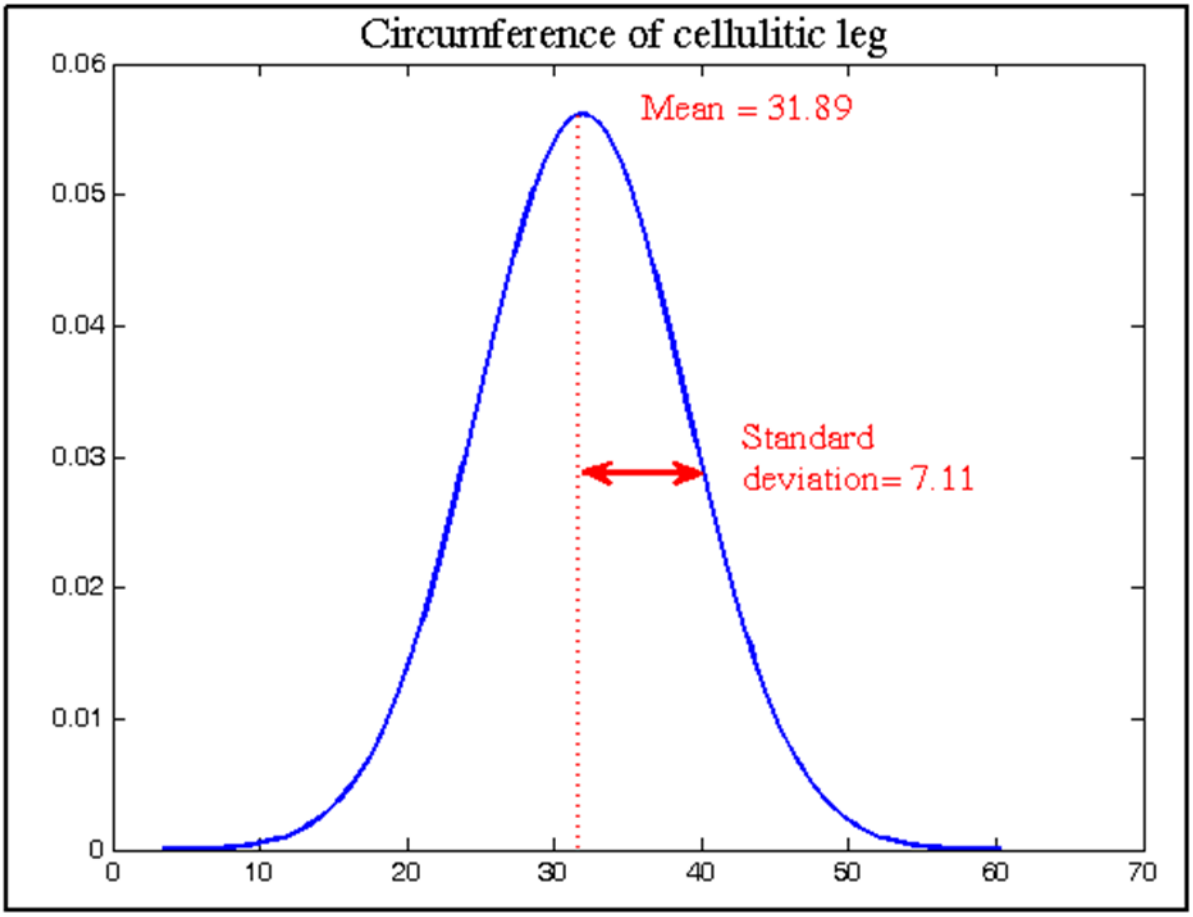

Fig 10: Bell curve showing the distribution of circumference of the cellulitic leg with mean of 31.89cm and standard deviation of 7.11.

The mean circumference of the cellulitic leg was 31.89cm. There was increase in circumference of the cellulitic leg when compared to the normal leg as shown in Table 5.

SUBCUTANEOUS PRESSURE

Measures	Normal leg pressure	Maximum pressure in cellulitic leg	Change in pressure
Mean	2.29	9.39	7.11
Minimum	-4	4	2
Maximum	6	16	16
SD	3.05	3.40	2.95
25^{th} percentile	-5.00	7.00	4.25
50^{th} percentile	3.00	9.00	7.50
75^{th} percentile	5.00	12.00	9.00

Table 6: Subcutaneous pressures in normal leg, cellulitic leg and the increase in subcutaneous pressure documented as change in pressure.

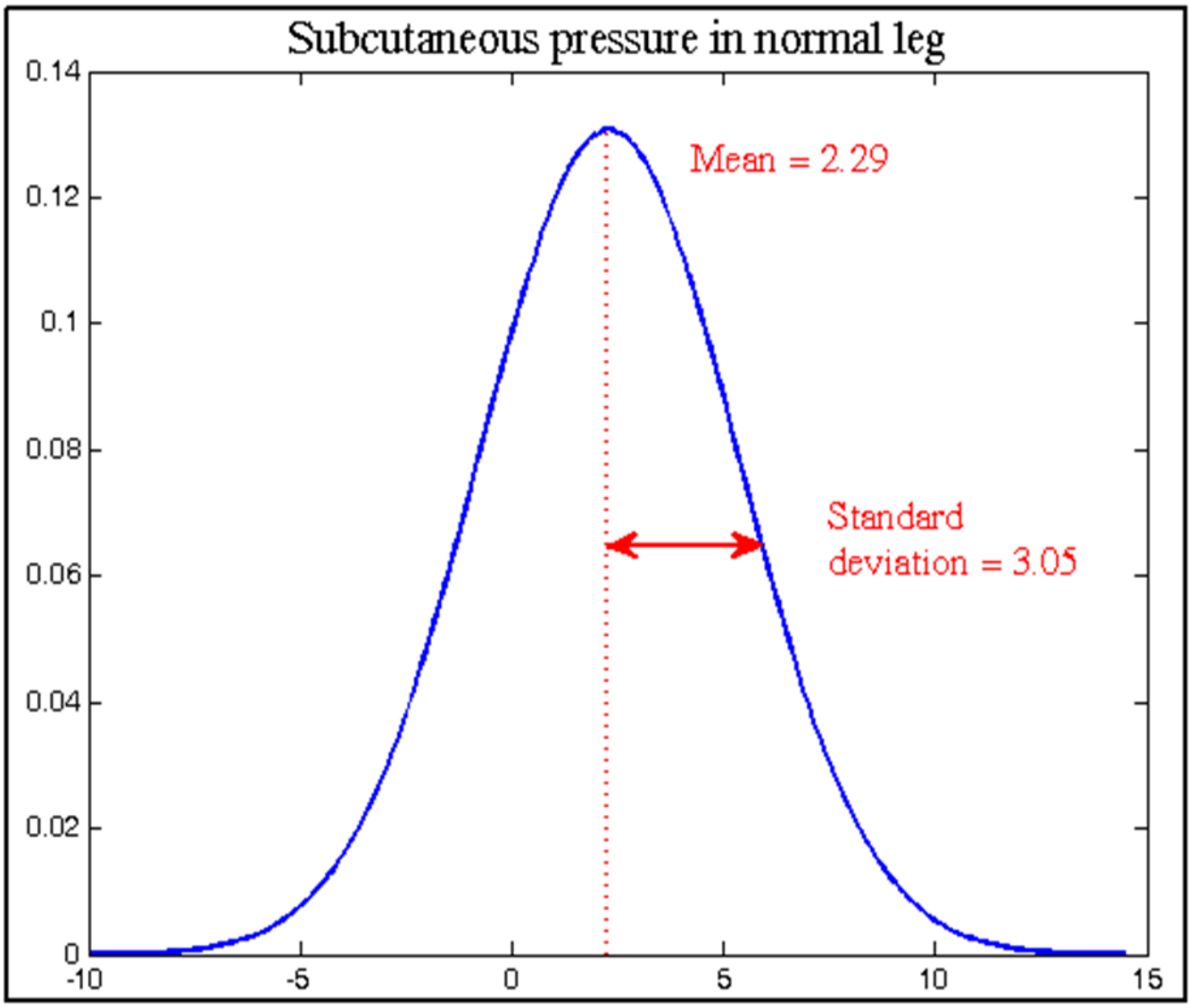

Fig 11: Bell curve showing the normal distribution of subcutaneous pressure in normal leg with the mean of 2.29mmHg

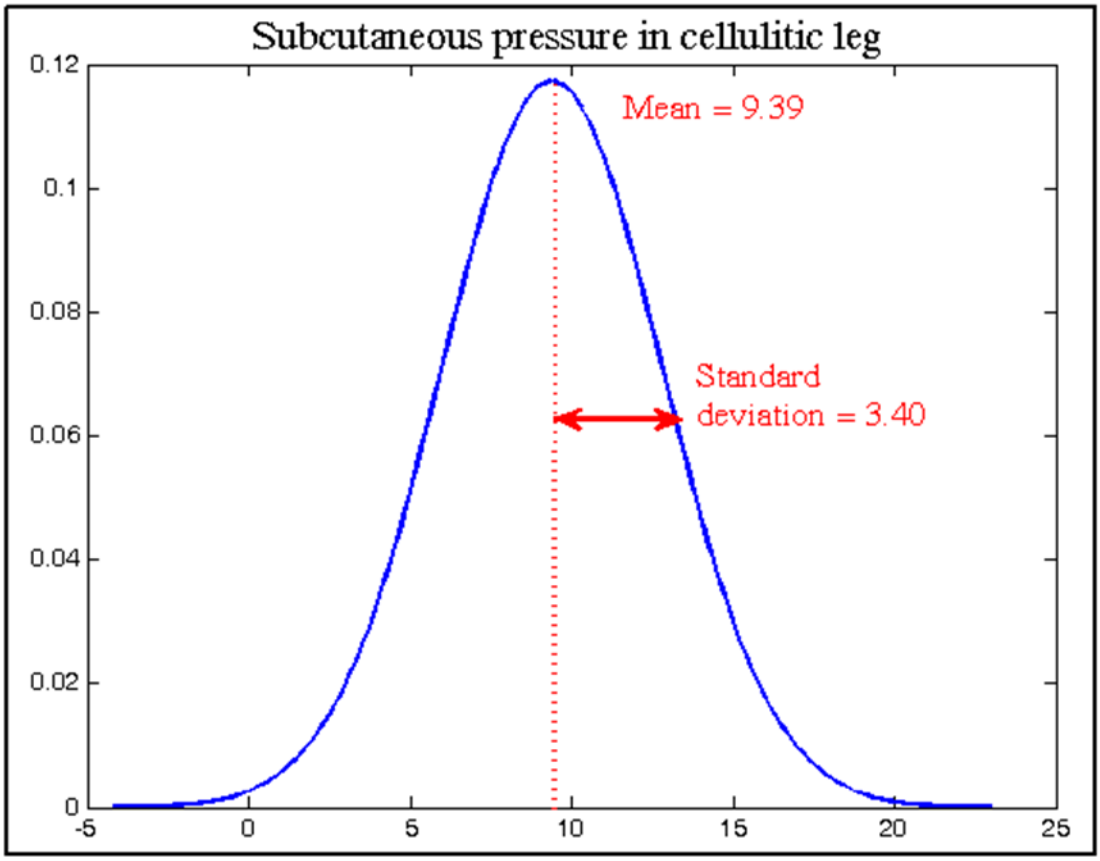

Fig 12: Bell curve showing the normal distribution of subcutaneous pressure in the cellulitic leg with mean of 9.39mmHg.

The maximum subcutaneous pressure in the cellulitic leg corresponded to the area of cellulitis. There was increase in subcutaneous pressure in the cellulitic leg when compared to the normal leg. The difference between the maximum subcutaneous pressure in cellulitic leg and subcutaneous pressure of the normal leg was documented as change in pressure as shown in Table 6.

Cir	Circum	SP-NL	SAM	SAL	SPM	SPL	DIS
35	42	-2	6	5	7	5	14
35	38	-3	7	6	7	6	12
30	38	5	9	5	9	10	13
29	32	3	4	12	5	10	11
33	41	4	11	11	8	8	13
27	30	6	13	16	10	16	13
32	36	3	8	11	6	6	13
11	13	6	10	8	10	11	4
31	36	2	4	3	10	2	14
34	38	4	4	8	4	7	14
29	32	-1	4	1	6	1	12
23	26	2	10	6	11	6	18
40	44	5	14	5	5	6	15
36	41	-4	11	8	12	6	16
29	31	5	11	7	13	6	15
27	32	4	14	6	4	4	18
27	31	4	8	7	6	4	15
23	27	-3	3	5	1	1	17
31	34	3	3	7	3	6	15
25	27	2	5	5	3	2	15
35	38	1	3	4	4	3	15
24	28	4	8	4	5	4	24
31	35	5	13	11	10	9	20
23	26	6	9	8	15	13	27
19	22	-1	6	4	5	4	26
19	22	-2	5	3	4	3	30
26	28	1	4	1	7	2	21
22	25	5	4	7	4	7	20

Table 7: Circumference and pressure values in normal and cellulitic leg

Cir – circumference of normal leg, Circum – circumference of the cellulitic leg

SP-NL – subcutaneous pressure of the normal leg,

SAM- subcutaneous pressure in the anteromedial aspect of cellulitic leg,

SAL- subcutaneous pressure in the anterolateral aspect of cellulitic leg,

SPM- subcutaneous pressure in the posteromedial aspect of cellulitic leg,

SPL – subcutaneous pressure in the posterolateral aspect of cellulitic leg and

Dis – distance from the tibial tuberosity.

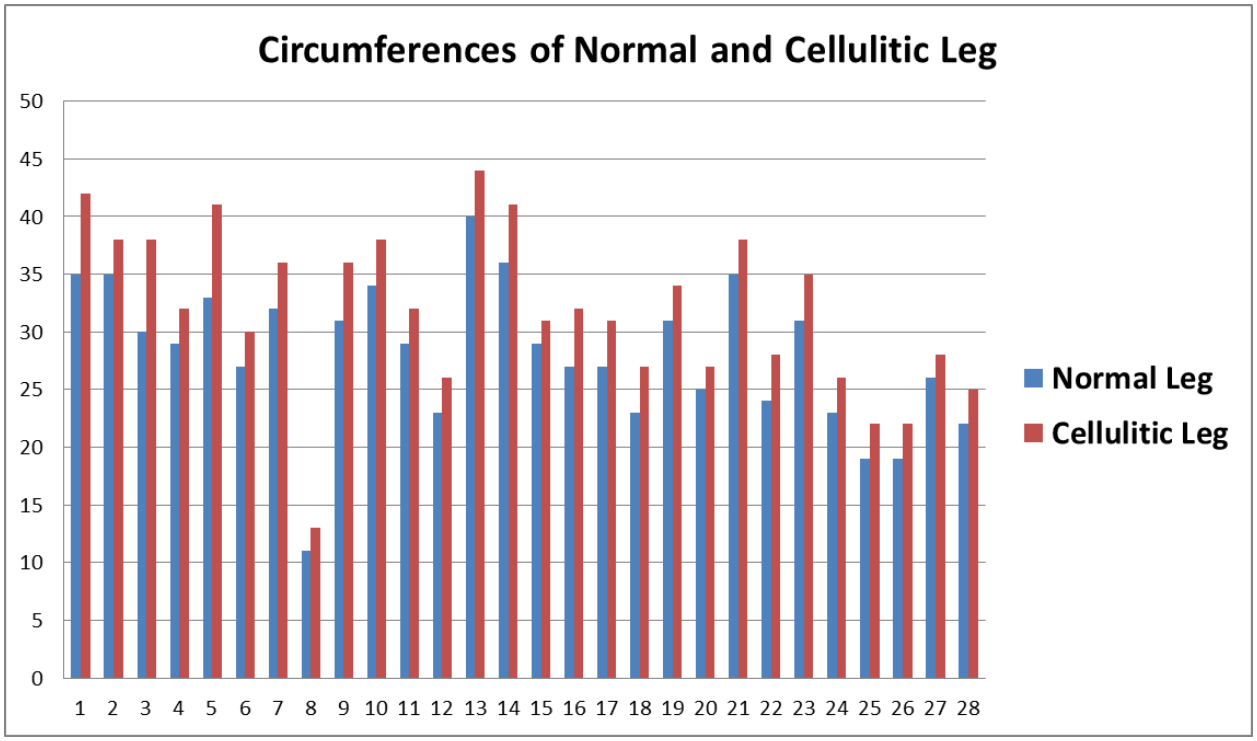

Fig 13: Histogram of circumferences of normal and cellulitic leg

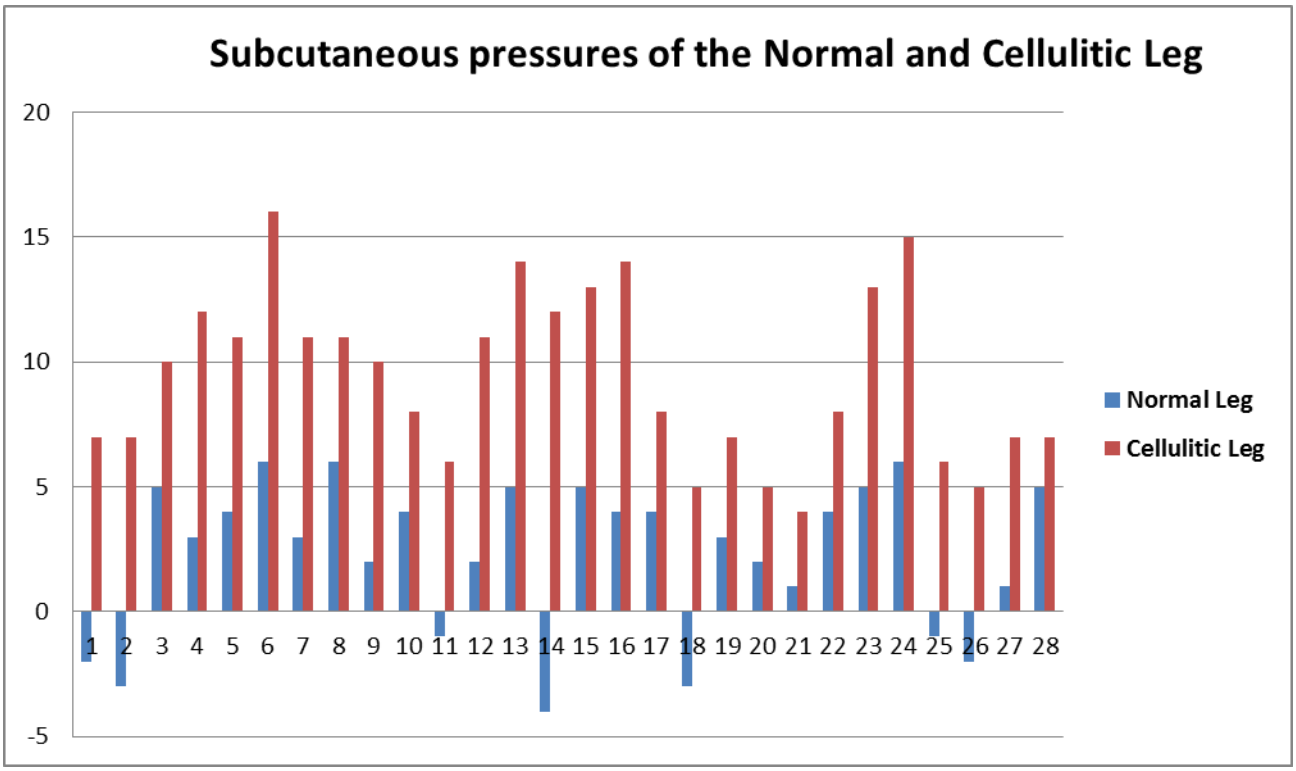

Fig 14: Histogram of subcutaneous pressures of the normal and cellulitic leg

Table 7 lists the subcutaneous pressure measured at 4 points in the cellulitic leg to find out if there is any statistical difference between the subcutaneous pressure in anteromedial, posteromedial, anterolateral and posterolateral aspect of the cellulitic leg. This analysis was performed as in most of the cellulitic leg the swelling was confined to one aspect and considering subcutaneous space as a closed single compartment the pressure was anticipated to be equally distributed. At the end of the analysis there was no statistical significant difference between the subcutaneous pressure in the anterior, posterior, medial and lateral aspect of the leg as shown in Table 8 and Table 9. Even though there was no statistically significant difference in subcutaneous pressure at 4 points, the highest subcutaneous pressure corresponds to the area of cellulitis.

STASTICAL SIGNIFICANCE

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair	AM_AL - PM_PL	1.17857	4.68294	.88499	-.63728	2.99442	1.332	27	.194

Table 8: Paired t- test is used to analyze the statistical significance in the difference of subcutaneous pressure between anterior and posterior aspect of the cellulitic leg. AM- anteromedial, AL – anterolateral, PM- posteromedial, PL- posterolateral

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair	AM_PM - AL_PL	1.89286	6.11821	1.15623	-.47954	4.26525	1.637	27	.113

Table 9: Paired t-test is used to analyze the statistical significance in the difference of subcutaneous pressure between medial and lateral aspect of the cellulitis leg. AM- anteromedial, AL – anterolateral, PM- posteromedial, PL- posterolateral

CORRELATION

The subcutaneous pressure was correlated to the circumference of the leg and to the distance from tibial tuberosity. This correlation was done as different patients had cellulitis at varying distance from the tibial tuberosity. These values were statistically analyzed to find out the significance. The correlation between increase in the circumference of cellulitic leg and the subcutaneous pressure was analyzed using Scatter plot graph. There was no positive correlation as the plots were scattered probably due to small sample size as shown in Fig 15.

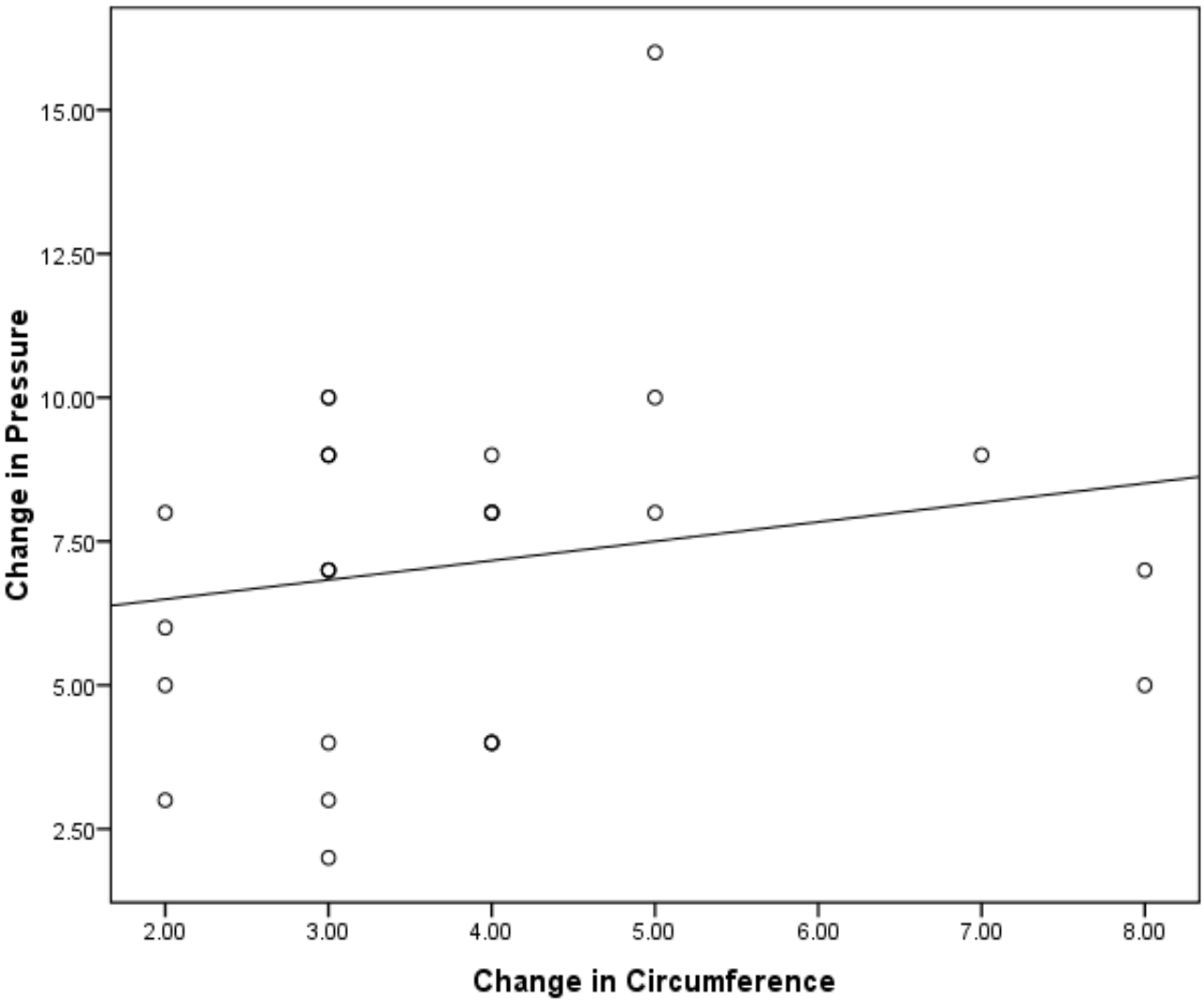

Fig 15: Scatter plot graph showing the correlation between the increase in circumference of the cellulitis leg to the change in pressure.

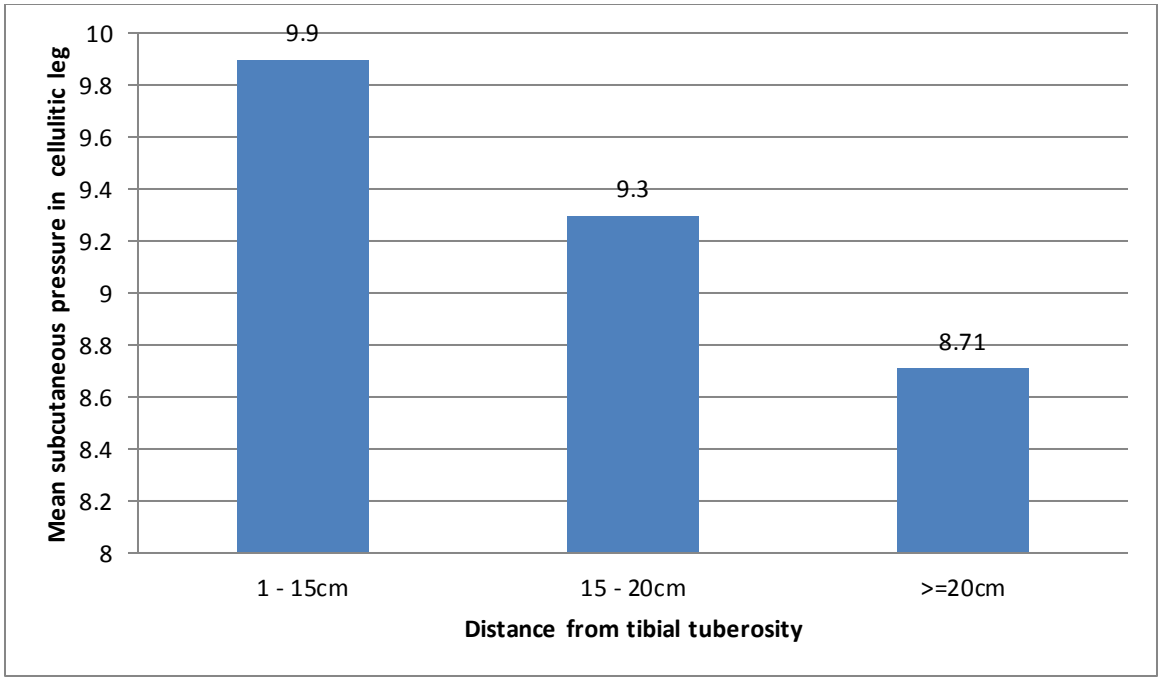

Fig 16: Bar chart showing the mean subcutaneous pressure in the cellulitic leg with respect to the distance from tibial tuberosity.

The distance from tibial tuberosity was different for different individuals. But there was no statistically significant difference in subcutaneous pressure with respect to distance from tibial tuberosity.

TREATMENT

All patients were treated with antibiotic, anti-inflammatory medications, limb elevation and magnesium sulphate paste local application. The antibiotics most commonly used were parenteral Penicillin and Cloxacillin. One patient was treated with Cefazolin and 3 patients who progressed to necrotizing soft tissue infection with systemic sepsis were treated with Piperacillin-Tazobactamand Clindamycin. The antibiotic was chosen according to the treating surgeon decision.

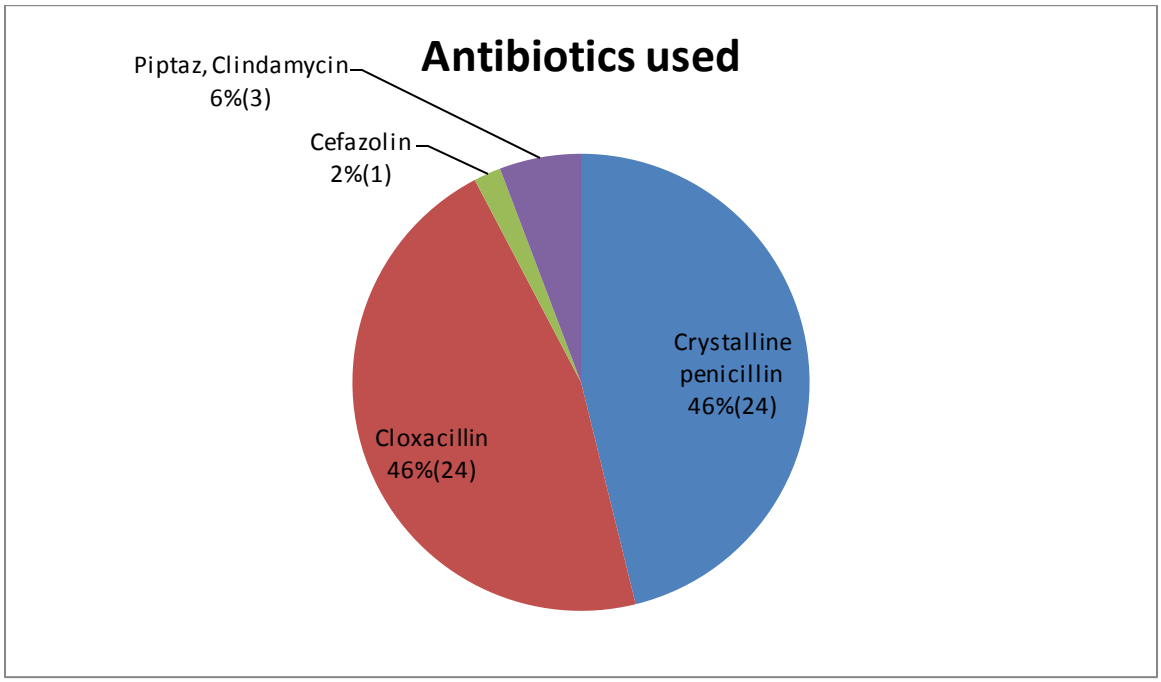

Fig 17: Pie chart showing the percentage of antibiotics used in the treatment of cellulitis in the study population

GROUP STATISTICS

Group	N	Mean	Std Deviation	Std. Error Mean
Antibiotics & Surgery	14	8.2857	2.75761	0.73700
Antibiotics only	14	5.9286	2.73058	0.72978

Table 10: Group statistics of patients treated only with antibiotic and treated with antibiotic and surgery

The increase in subcutaneous pressure in the cellulitic leg when compared to the normal leg was correlated with the treatment given. One group of patients (N = 14) were managed conservatively with antibiotic. The other 14 patients underwent surgical intervention out of which 2 were operated within 24 hours of admission and 12 were operated later due to failure of conservative management. The results are shown in Table 10.

The mean of change in pressure was 8.29 mmHg in the group of patients who had surgical intervention and it was 5.93mmHg in the group treated with antibiotic. The mean increase in subcutaneous pressure in cellulitic leg was more in group treated with antibiotic and surgery.

	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	T	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
								Lower	Upper
Change_pre Equal variances	0.881	0.357	2.273	26	0.032	2.35714	1.03718	0.22519	4.48910
Assumed Equal variances not assumed			2.273	25.997	0.032	2.35714	1.03718	0.22518	4.48911

Table 11: Test of significance is shown for the increase in subcutaneous pressure between the group treated with antibiotic and the group treated with surgery& antibiotic. There is a statistical significant change in subcutaneous pressure between two groups.

The increase in subcutaneous pressure in cellulitic leg when compared to the normal leg was more in group of patients treated with surgery and antibiotic. **The change in subcutaneous pressure was statistically significant between two groups with p value of 0.032.**

FOLLOW UP

The patients were followed up at the time of discharge and 14th day in the outpatient clinic. One elderly male patient who had multiple medical comorbidities with cellulitis progressed to necrotizing soft tissue infection. His subcutaneous pressure in the cellulitic leg was high at the time of admission. He was managed conservatively but due to the failure of conservative management, he underwent debridement on 3rd day. During this course he had worsening systemic sepsis with multiple organ failure and died. There was a readmission for a patient who was treated initially with antibiotics and underwent surgery during the second admission. His subcutaneous pressure was also high at the time of first admission. The clinical indicators like pain, swelling, tenderness were assessed during the follow up to document the improvement as shown in Fig 18 & Fig 19. Patients who underwent surgery had raw area for which they required regular dressings.

Clinical indicators	Fever	Swelling	Pain
No of patients	1	7	9

Table 12: Clinical assessment at the time of discharge.

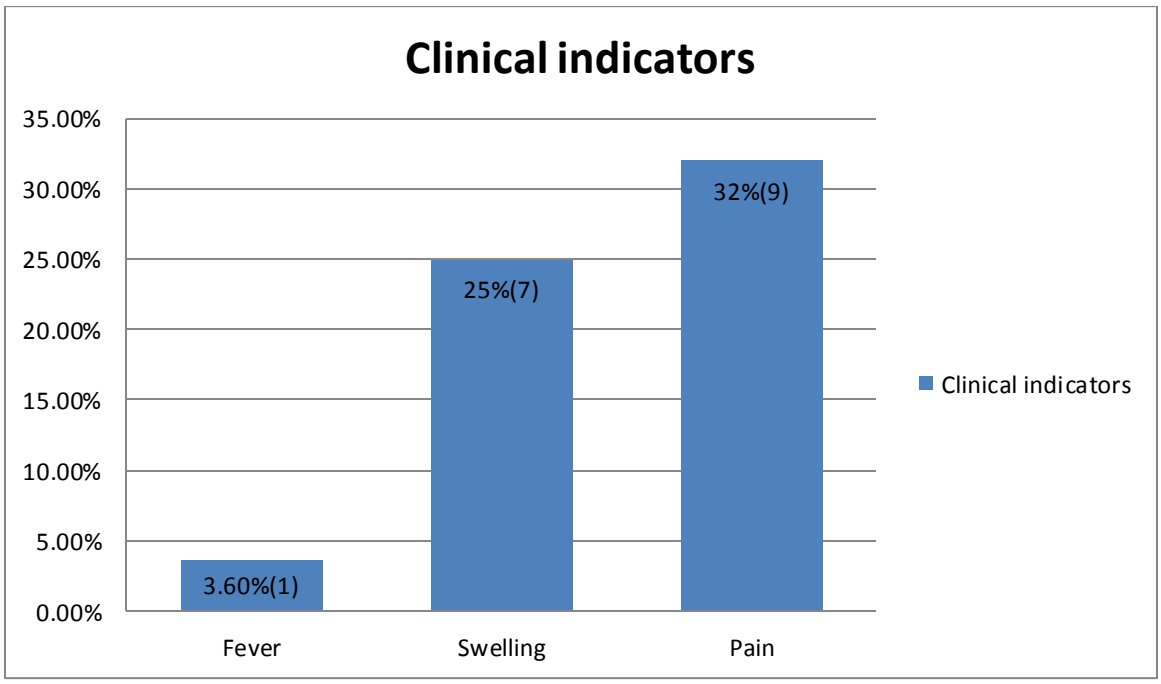

Fig 18: Clinical assessment at the time of discharge

During follow up at the time of discharge there was decrease in swelling and pain in majority of the study group. One patient had complaints of low grade fever. He was discharged with oral antibiotics and advised to continue limb elevation at home. But due to the ascending infection, he was readmitted and underwent debridement.

.

Symptoms	Pain	Swelling	Fever
At admission	100%	100%	96%
At discharge	32%	25%	3.6%
On 14th day	7.1%	3.6%	3.6%

Table 13: Percentage of patients with the symptoms above mentioned at the time of admission, discharge and on 14th day of follow up

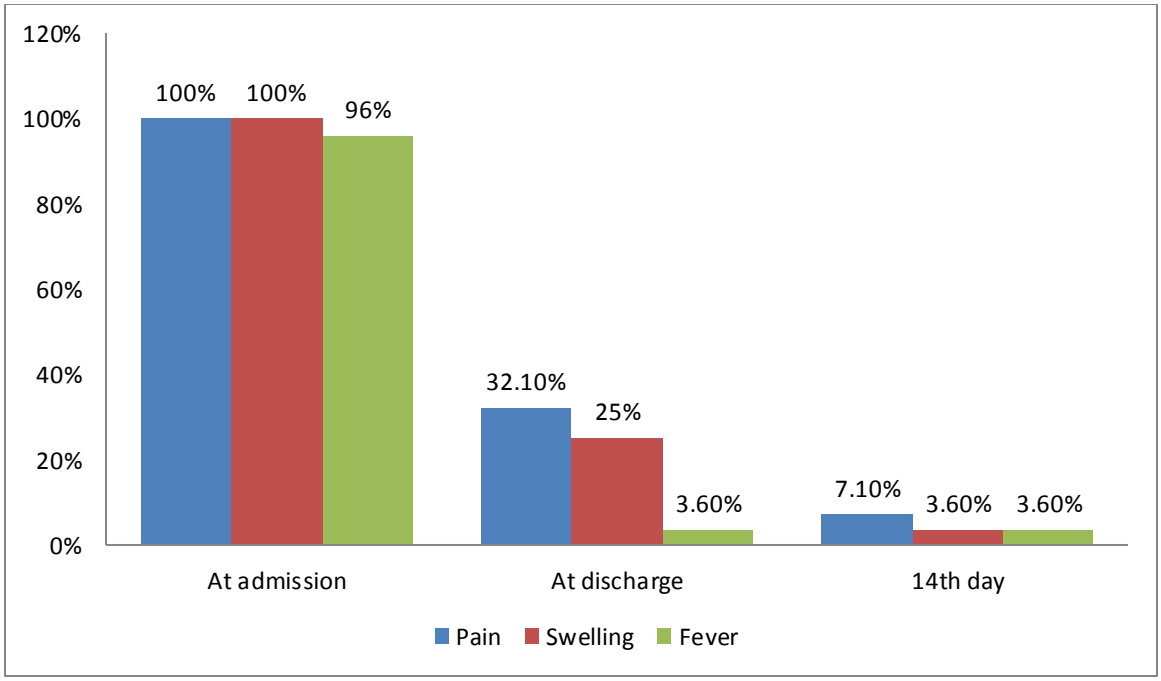

Fig 19: Bar chart showing the percentage of clinical indicators at the time of admission, discharge and 14th day of follow up in both groups.

The clinical assessment at the time of discharge and during follow up on 14th day showed improvement with respect to pain, swelling and fever as shown in Fig 19.

6. DISCUSSION

6. DISCUSSION

Current guidelines recommend conservative management for cellulitis, which includes antibiotic, anti-inflammatory medications and anti-edema measures. If there is an ascending infection with systemic sepsis or necrotizing soft tissue infection, surgical intervention is usually undertaken. The decision for the surgical intervention in severe cellulitis with skin changes are made by the treating surgeon based on subjective assessment. There are no standardized criteria for the surgical intervention in cellulitis of the leg.

The attempt of measuring the subcutaneous pressure and correlating to the surgical intervention was done mainly to define criteria for surgical intervention. This study revealed that the patients who had surgical intervention, the subcutaneous pressure in the cellulitic leg was significantly high when compared to the patients who were managed conservatively.

The measurement of subcutaneous pressure at the time of admission will be useful in deciding the treatment option. The patients who had high subcutaneous pressure at the time of admission ended up in surgery later due to failure of conservative management. In this group of patients, early surgical

intervention can prevent ascending infection with systemic sepsis, extensive debridement due to progressing necrotizing soft tissue infection and avoid prolonged use of antibiotics and hospital stay.

7. CONCLUSION

7. CONCLUSION

From this study, it is proven that the subcutaneous pressure is increased in cellulitic leg. The increase in subcutaneous pressure is associated with more local complications. The patients with high subcutaneous pressure were treated with surgical intervention on the same day of admission or later due to failure of conservative management. So the surgical intervention in cellulitis of the leg is correlating with increased subcutaneous pressure in cellulitis of the leg.

8. FUTURE RESEARCH AND LIMITATIONS

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FUTURE RESEARCH

From this study, it was difficult to define a target pressure at which the surgical intervention is needed due to small sample size. However a larger study with more numbers will be helpful to ascertain the subcutaneous pressure criteria for surgical intervention.

LIMITATIONS

The measurement of subcutaneous pressure with Stryker intracompartmental pressure monitor is operator dependent. The depth of needle insertion and the angulation can alter the pressure values which can lead to interobserver variability

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ANNEXURE

Annexure 1

Proforma

- NAME:
- AGE:
- SEX:
- HOSPITAL NUMBER:
- ADDRESS :

- PHONE NO:
- EMAIL ID:
- COMPLAINTS:

- DURATION :
- CO MORBIDITIES:

- GENERAL EXAMINATION:

- VITALS: PR - , RR - , TEMP- , BP- .

- SYSTEMIC EXAMINATION:

- LOCAL EXAMINATION :
    - SWELLING-
    - ERYTHEMA -
    - WARM –
    - TENDERNESS –

- DIAGNOSIS :

- CIRCUMFERENCE OF CELLULITIS LEG :
- CIRCUMFERENCE OF NORMAL LEG :
- SUBCUTANEOUS PRESSURE :

  NORMAL LEG (ANTEROMEDIAL):

  CELLULITIS LEG -
    - ANTEROMEDIAL:
    - ANTEROLATERAL:
    - POSTEROMEDIAL:
    - POSTEROLATERAL:

- DISTANCE FROM TIBIAL TUBEROSITY :
- MANAGEMENT:

- FOLLOW UP:
    - AT THE TIME OF DISCHARGE:

    - 14^{th} DAY:

- EXTRA DETAILS :

Annexure 2

PATIENT INFORMATION SHEET

Cellulitis is an infection of skin and subcutaneous tissue. This is usually a bacterial infection which can enter the subcutaneous space either through the skin wound or from blood. Once the infection enter the subcutaneous space ,due to bodys response there will be fluid accumulation in subcutaneous space with pain, swelling , redness and fever .This fluid accumulation can cause increase in subcutaneous pressure and can act as a medium for the infections to grow and can cause skin ulcers or it can spread into deeper tissues causing life threatening complications .So it is important to decide the severity of cellulitis with respective to increase in subcutaneous pressure and the pressure at which surgical intervention is needed . So in this study I am going to measure the subcutaneous pressure in the Cellulitis leg and in the normal leg for the purpose of comparison. The subcutaneous pressure is measured with a handheld pressure monitor. It is an invasive test in which skin is pricked at five sites, one in the normal leg and the other four sites in the Cellulitis leg. The sites where needle is inserted are marked and its distance from nearby bony prominence is measured with an inch tape. This test can cause pain similar to the pain experienced while taking the blood sample for blood tests .There is chance of spreading of infection into deeper tissue but it is minimized by starting the first dose of antibiotics and inserting the needle at angle of 45 degree with the skin. This entire procedure is done under aseptic precautions that is both the legs are cleaned with betadineand covered with sterile cloth. Please give your consent to participate in this study.

“Thank you for being a part of this study.”

Investigator name-

Signature -

Annexure 3

CONSENT FORM

TITLE : STUDY OF SUBCUTANEOUS PRESSURE IN CELLULITIS OF THE LEG AND ITS CORRELATION TO THE MANAGEMENT

Patient name: Hospital no:

Age in years: Sex:

Date:

I,……..,
son/daughter

of ……..

- Declare that I have read the information sheet provided to me regarding this study and clarified any doubts that I had.
- I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or legal rights.
- I understand that I will not receive any financial compensation for participation in this study
- I understand that my identity will not be revealed in any information released to third parties or published.
- I voluntarily agree to take part in this study.

Name: ……..

Signature: ……

Name of witness:……

Signature of witness: ……..

Relation to patient: ……

Thumb Impression:

Name of investigator:

Signature

Annexure 4

Data sheet

hno	Age	sex
514073c	57.00	1.00
970674d	57.00	1.00
347768f	62.00	1.00
953778c	51.00	2.00
738325c	77.00	1.00
308120c	62.00	1.00
259352f	56.00	1.00
194401f	41.00	1.00
752733b	70.00	1.00
918843a	73.00	1.00
760192d	63.00	1.00
299236f	65.00	2.00
312344b	43.00	1.00
781612d	66.00	1.00
009167f	27.00	1.00
259534f	67.00	1.00
118864a	58.00	2.00
011383f	65.00	1.00
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688755f	64.00	1.00
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476285a	52.00	1.00
636021b	81.00	1.00
753561d	57.00	1.00
103204a	54.00	2.00

pai	swe	Fev	dura
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1.00	1.00	1.00	7.00
1.00	1.00	1.00	7.00
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1.00	1.00	1.00	7.00
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1.00	1.00	1.00	7.00
1.00	1.00	1.00	4.00
1.00	1.00	1.00	10.00
1.00	1.00	1.00	7.00
1.00	1.00	1.00	3.00
1.00	1.00	1.00	7.00
1.00	1.00	0.00	10.00
1.00	1.00	1.00	7.00
1.00	1.00	1.00	5.00
1.00	1.00	1.00	5.00
1.00	1.00	1.00	5.00
1.00	1.00	1.00	10.00

dm	ht	crf	pal	pe	pr	Bp
1.00	0.00	0.00	0.00	0.00	98.00	110.70
1.00	0.00	0.00	0.00	0.00	82.00	130.90
1.00	0.00	0.00	0.00	0.00	94.00	130.90
0.00	0.00	0.00	0.00	0.00	98.00	100.60
1.00	1.00	0.00	0.00	0.00	90.00	130.70
0.00	0.00	0.00	0.00	0.00	99.00	120.70
0.00	0.00	0.00	0.00	0.00	98.00	100.60
0.00	0.00	0.00	0.00	0.00	80.00	100.60
1.00	0.00	1.00	1.00	0.00	98.00	120.80
1.00	1.00	0.00	0.00	0.00	98.00	140.80
1.00	0.00	0.00	0.00	0.00	90.00	120.80
0.00	0.00	0.00	1.00	0.00	98.00	100.60
0.00	0.00	0.00	0.00	0.00	80.00	110.70
1.00	0.00	1.00	1.00	0.00	80.00	110.70
0.00	0.00	0.00	0.00	0.00	99.00	100.80
0.00	0.00	0.00	0.00	0.00	72.00	120.80
1.00	0.00	0.00	0.00	0.00	96.00	120.70
1.00	0.00	0.00	0.00	0.00	98.00	120.80
1.00	0.00	0.00	0.00	0.00	96.00	130.80
1.00	0.00	0.00	0.00	0.00	96.00	120.80
1.00	1.00	1.00	0.00	0.00	90.00	110.70
0.00	1.00	0.00	0.00	0.00	90.00	110.70
0.00	0.00	0.00	0.00	0.00	99.00	110.70
1.00	0.00	0.00	0.00	0.00	98.00	140.60
1.00	0.00	0.00	0.00	0.00	99.00	110.70
1.00	1.00	1.00	1.00	0.00	88.00	100.60
1.00	1.00	0.00	1.00	1.00	68.00	120.80
1.00	0.00	0.00	0.00	0.00	98.00	150.80

swe1	ery	war	Ten	cr	cir
1.00	1.00	1.00	1.00	35.00	42.00
1.00	0.00	1.00	1.00	35.00	38.00
1.00	1.00	1.00	1.00	30.00	38.00
1.00	1.00	1.00	1.00	29.00	32.00
1.00	1.00	1.00	1.00	33.00	41.00
1.00	1.00	1.00	1.00	27.00	30.00
1.00	1.00	1.00	1.00	32.00	36.00
1.00	1.00	1.00	1.00	11.00	13.00
1.00	1.00	1.00	1.00	31.00	36.00
1.00	1.00	1.00	1.00	34.00	38.00
1.00	0.00	1.00	1.00	29.00	32.00
1.00	1.00	1.00	1.00	23.00	26.00
1.00	1.00	1.00	1.00	40.00	44.00
1.00	0.00	1.00	1.00	36.00	41.00
1.00	0.00	1.00	1.00	29.00	31.00
1.00	1.00	1.00	1.00	27.00	32.00
1.00	1.00	1.00	1.00	27.00	31.00
1.00	1.00	1.00	1.00	23.00	27.00
1.00	0.00	1.00	1.00	31.00	34.00
1.00	1.00	1.00	1.00	25.00	27.00
1.00	1.00	1.00	1.00	35.00	38.00
1.00	1.00	1.00	1.00	24.00	28.00
1.00	0.00	1.00	1.00	31.00	35.00
1.00	1.00	1.00	1.00	23.00	26.00
1.00	1.00	1.00	1.00	19.00	22.00
1.00	1.00	1.00	1.00	19.00	22.00
1.00	1.00	1.00	1.00	26.00	28.00
1.00	1.00	1.00	1.00	22.00	25.00

sp	sam	sal	Spm	spl	dis
-2.00	6.00	5.00	7.00	5.00	14.00
-3.00	7.00	6.00	7.00	6.00	12.00
5.00	9.00	5.00	9.00	10.00	13.00
3.00	4.00	12.00	5.00	10.00	11.00
4.00	11.00	11.00	8.00	8.00	13.00
6.00	13.00	16.00	10.00	16.00	13.00
3.00	8.00	11.00	6.00	6.00	13.00
6.00	10.00	8.00	10.00	11.00	4.00
2.00	4.00	3.00	10.00	2.00	14.00
4.00	4.00	8.00	4.00	7.00	14.00
-1.00	4.00	1.00	6.00	1.00	12.00
2.00	10.00	6.00	11.00	6.00	18.00
5.00	14.00	5.00	5.00	6.00	15.00
-4.00	11.00	8.00	12.00	6.00	16.00
5.00	11.00	7.00	13.00	6.00	15.00
4.00	14.00	6.00	4.00	4.00	18.00
4.00	8.00	7.00	6.00	4.00	15.00
-3.00	3.00	5.00	1.00	1.00	17.00
3.00	3.00	7.00	3.00	6.00	15.00
2.00	5.00	5.00	3.00	2.00	15.00
1.00	3.00	4.00	4.00	3.00	15.00
4.00	8.00	4.00	5.00	4.00	24.00
5.00	13.00	11.00	10.00	9.00	20.00
6.00	9.00	8.00	15.00	13.00	27.00
-1.00	6.00	4.00	5.00	4.00	26.00
-2.00	5.00	3.00	4.00	3.00	30.00
1.00	4.00	1.00	7.00	2.00	21.00
5.00	4.00	7.00	4.00	7.00	20.00